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Section 5: 510(k) Summary

Date Prepared: July 18, 2012

510(k) Number: K 122154

Sponsor

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Device Name

Trade Name: PowerPlay
Model Number: PPRT-01
Common or Usual Name: Inflatable Leg Massager
Proprietary Name: PowerPlay Muscle Massager
Classification Name: Powered Inflatable Tube Massager
Class II
Product Code: IRP
Regulation Number: 21 CFR 890.5650

Identification of Predicate Devices

King Tai Holdings, Ltd., Verseo Leg Massager	K092435
Nihon Seimitsu Sokki Co., Ltd., Portable Air Massager	K071596
Salton, Inc., Relaxor Perfect Touch Air Massaging System	K030437

Device Description

The PowerPlay Muscle Massager is a lightweight, portable, rechargeable battery powered **OTC device** that is intended to be used by individuals to relieve minor muscular aches and pains and to temporarily increase blood circulation in the treated areas.

The system utilizes pneumatically controlled, single bladder compression wraps actuated by an electronically controlled air pump unit and solenoid valves. The intermittent compression provided by the system simulates stroking and kneading of the tissue by the hands. All pump, battery and control components are protectively housed in a plastic case. A mylar control panel overlays 4 tactile touch control switches, an LED display for monitoring pressure, LED "selected channel", "low battery" and "charging" indicators. There is also a port for connecting the battery charger/AC adapter plug.

The compression wraps consist of a Polyvinyl Chloride (PVC) air bladder encased inside soft, non-woven medical fabric (made from Polyester or Softesse – a fabric composed of common kitchen sponge material), which is adhered to the PVC air bladder. The wraps are supplied clean, non-sterile, packaged individually. A calf, ankle, knee, hip or shoulder massage wrap may be supplied with the PPRT -01 system or available as accessory items.

In operation, the user selects any number of 3 different outputs (Port 1, Port 2 and/or Port 3) and sets the pressure desired for each port (30, 50 or 70 mmHg). An LED corresponding to each output indicates the selected ports, with the digital display indicating the pressure setting for each (see instructions for use). User determined compression wraps containing air bladders are connected to the unit via externally accessible plastic quick-disconnect air ports. The control unit then inflates the wraps to the preset pressure. The LED that corresponds to the activated output channel flashes slowly while that wrap is being filled with air. Wrap pressure is monitored by an integrated pressure transducer and system software. Once the pressure reaches the proper level, the pump is turned OFF for a predetermined "rest" period, and the wrap deflates to ambient pressure through a valve inside the plastic case. After the "rest" period, the next wrap is sequenced, and so on. This cycle repeats for 20 minutes on each output (preset treatment period) and then that output turns off. When all selected outputs have completed their 20 minute treatment period the unit powers off. The unit power can be turned off at any time by pressing and holding the I/O button for approximately 2 seconds.

The "rest" period is internally preset to allow each wrap approximately 30 seconds between inflations in order to ensure adequate deflation time between compressions. When multiple outputs are selected, only one wrap is inflated at a time.

Intended Use

The PowerPlay model PPRT-01 is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands by use of inflatable pressure wraps. This device can be used to:

- Temporarily increase blood circulation in the treated areas;
- Temporary relief of minor muscle aches and pains.

Contraindications

The PowerPlay model PPRT-01 ***must not*** be used by persons with the following conditions:

- Suspected, active or untreated: Neuropathy, deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, congestive heart failure, thrombophlebitis or an active infection;
- On a leg where wraps would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg;
- On extremities that are insensitive to pain;
- Where increased circulation is undesirable;

Comparison of Indications

The Indications for Use for the PowerPlay Muscle Massager are the same as those for the Verseo Leg Massager (K092435), Portable Air Massager (K071596) and Relaxor Perfect Touch (K030437) predicate devices listed.

Substantial Equivalence of Technological Characteristics

The PowerPlay Muscle Massager is equivalent to the predicate devices listed in operating principals to achieve identical results. That is, to provide massage by inflating and deflating massage garments wrapped around a part of the body. All systems, including the subject device, utilize microprocessor controlled pumps to deliver pressurized air to bladders that are attached to the user, using a cycle times of approximately 30 - 60 seconds. Each cycle consists of inflation of a bladder followed by a rest period during which the bladder deflates and the treated area relaxes without any compression.

The PowerPlay system uses similar means for pressure delivery to the wraps as the predicate devices. Pressurized air is delivered by the pump to the wraps. Although the Verseo unit (K092435) and the Portable Air Massager unit (K071596) incorporate the pump and wrap

into a single assembly, the PowerPlay delivers air to the wrap via flexible, plastic air tubes connected to the plastic pump / control unit by means of locking, quick disconnect couplings (like the Relaxor Perfect Touch (K030437). As with the Relaxor Perfect Touch, the PowerPlay Muscle Massager can be used with a variety of available compression wraps (i.e., shoulder, leg, etc.). All the predicate wraps, as well as those available for use with the PowerPlay system, are comprised of single bladder PVC chambers encased in a covering of soft, non-latex, non-woven medical fabric for increased patient comfort and biocompatibility compliance.

A difference in the subject device from all the predicates is that the PowerPlay unit has provisions for up to 3 separate massage wraps to be used at the same time. If more than one wrap is being used, the additional outputs are cycled during the rest period of the first output, keeping a constant cycle time of approximately 30 seconds for each. Each output port is independently limited to a 20 minute treatment time.

Cycle and treatment session times are factory preset and cannot be changed (predicate devices vary cycle and session times with selection of preset programs, except that the Perfect Touch system has a preset 15 minute treatment session time). Pressure settings on the predicate devices are adjusted automatically (dependent on the selected program) at levels between 45 and 320 mmHg, whereas the PowerPlay pressure is selectable to one of 3 preset levels (30, 50 and 70 mmHg).

Unlike the predicate systems, the microprocessor and pump unit is powered by internal rechargeable batteries, and can be connected to the main AC power line (through the battery charger / AC adaptor) while in use, allowing uninterrupted prolonged service. The Relaxor Perfect Touch must be connected to an AC adaptor during use, while the Verseo and Portable Air Massager units are powered from commonly available disposable consumer batteries.

A subtle difference between the predicate devices and the PowerPlay is in their respective alarm functions. Although all units are equipped with safety alarms, their functions differ somewhat. The subject device includes multiple audible and visual alarms including; High and low pressure alarms, low battery alarm and system malfunction overpressure safety via an internal safety vent with a release pressure of 2 psi (approximately 100 mmHg).

The management of FIG, LLC has reviewed these differences between the PowerPlay and those predicates cited and concluded that they pose no safety or efficacy concerns.

A detailed comparison table can be found in Section 10, Executive Summary, of this submission.

Non-Clinical Testing

Non-clinical validation, including electrical safety, EMC, mechanical integrity, environmental and life cycle testing have shown that the PowerPlay Muscle Massager has performance characteristics substantially equivalent to or surpassing those of the listed predicate devices. In-house bench testing has verified equivalent pressure delivery and wrap (bladder) fill time to the low pressure settings of the Relaxor Perfect Touch and Nihon Portable Air Massager, with overall system operation substantially equivalent to all predicate devices listed.

An informal focus group study was conducted by the sponsor in which the proposed Instructions for Use, a PowerPlay unit and various available site wraps were supplied to the participants for the purposes of determining the adequacy of the IFU. Most respondents reported the ability to use the device without referencing the IFU, with none of the participants reporting any difficulty in use with the aid of the proposed Instructions for Use.

Clinical Testing

No formal clinical testing was performed on the PowerPlay Muscle Massager.

Summary Conclusion

Per the requirements of 21 CFR 807, non-clinical validation testing and the information provided in the accompanying 510(k) submission, Fig, LLC concludes that the PowerPlay model PPRT-01 (with accessory compression wraps) is safe, effective and performs in a manner that is substantially equivalent to the predicate devices listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Fig, LLC
% Mr. Joe Adkins
Safeguard Manufacturing & Development, Inc.
2839 Harvest Moon Drive
Orange Park, FL 32073

Letter Dated: November 21, 2012

Re: K122154
Trade/Device Name: PowerPlay Muscle Massager, PPRT-01
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: October 10, 2012
Received: October 12, 2012

Dear Mr. Joe Adkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) # K K122154

Indications for Use:

The PowerPlay model PPRT-01 is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs. This device can be used to:

- Temporarily increase blood circulation in the treated areas;
- Temporary relief of minor muscle aches and pains.

Prescription Use: _____ **AND/OR** **Over-The-Counter Use:** X
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122154